The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 53

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANDREW D. BAROFSKY
and
KENTON W. GREGORY

Appeal No. 2005-0419
Application No. 08/797,770

ON BRIEF

Before KIMLIN, WALTZ, and DELMENDO, Administrative Patent Judges.
WALTZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the primary examiner's final rejection of claims 1 through 13, 15 through 24, 36 through 39, 41 through 55, 74, 76 through 100, 103 and 104. The remaining claims pending in this application are claims 101 and 102, which have been allowed by the examiner (Answer, page 2, ¶(3)). We have jurisdiction pursuant to 35 U.S.C. § 134.

According to appellants, the invention is directed to a method for producing a biomaterial fused onto a tissue substrate.

The method comprises providing a layer of biomaterial consisting essentially of tropoelastin aligned with one surface of a tissue substrate, and applying an energy absorbing material that penetrates into the interstices of the biomaterial (Brief, pages 3-4).[1] The energy absorbing material is then irradiated with light energy in a predetermined wavelength range with an intensity sufficient to fuse together one of the surfaces of the biomaterial and the tissue substrate (Brief, page 4). A method for producing the biomaterial is also claimed (see claim 47; Brief, page 7).

Appellants state that the claims should be considered as five separate groups, each group corresponding to the claims rejected in the five grounds of rejection in the final Office action (Paper No. 37, dated Sep. 11, 2002)(Brief, pages 10-11). As to the grounds of rejection remaining in this appeal (see the Answer, pages 2-3, ¶(6)), we consider one claim from each group, with the remaining claims in each group standing or falling together. See 37 CFR § 1.192(c)(7)(2002); *In re McDaniel*, 293 F.3d 1379, 1383, 63 USPQ2d 1462, 1465 (Fed. Cir. 2002). Representative independent claims 1 and 47 are reproduced below:

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[1]We refer to and cite from appellants' Amended Appeal Brief filed June 30, 2003.

1. A method for producing a biomaterial fused onto a tissue substrate comprising:

providing a layer of said biomaterial consisting essentially of tropoelastin having a first and second outer major surface and a tissue substrate having a first and second outer major surface; and

applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to a selected one of said first and second outer surfaces of the biomaterial in an amount which will cause fusing together of one said first and second outer surfaces of the biomaterial and one of said first and second outer surfaces of said tissue substrate, said energy absorbing material penetrating into the interstices of said biomaterial;

irradiating the energy absorbing material with light energy in said predetermined wavelength range with an intensity sufficient to fuse together one of said first and second outer surfaces of the biomaterial and the tissue substrate; and

fusing together the selected one of said first and second outer surfaces of the biomaterial and the tissue substrate.

47. A method for producing a biomaterial, which comprises: providing a polymerizable monomer consisting essentially of tropoelastin; polymerizing said polymerizable monomer to form a polymer consisting essentially of tropoelastin; and

forming a biomaterial consisting essentially of tropoelastin from said polymer.

The examiner has relied upon the following references, in addition to the admission in appellants' specification at page 1, ll. 12-23, as evidence of unpatentability:

Labroo et al. (Labroo)	5,428,014	June 27, 1995
Gregory (published International Application)	WO 96/14807	May 23, 1996

Claims 1-13, 15-24, 36-39, 41-55, 74, 76-100 and 103-104 stand rejected under 35 U.S.C. § 102(a) as anticipated by Gregory

or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Gregory in view of Labroo (Answer, page 4). Claim 47 stands rejected under 35 U.S.C. § 102(b) as anticipated by appellants' admission of prior art as stated at page 1, ll. 12-23, of the specification (Answer, page 5).[2]

Based on the totality of the record, including consideration of the Brief, Reply Brief, Answer, and Declarations under 37 CFR § 1.131 and § 1.132, we *affirm* all of the rejections on appeal essentially for the reasons stated in the Answer and those set forth below.

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[2]The final rejection of claims 24, 36-39, 41-55, 74, 76-98, and 100-104 under the second paragraph of § 112 has been withdrawn by the examiner (Answer, page 2, ¶(6), and page 5). The final rejection of claims 47, 48 and 53-55 under § 102(b) over Labroo has been withdrawn by the examiner (Answer, page 3, ¶(6), and page 8). The final rejection of claims 47-48 under § 102(b) over appellants' admitted prior art has been modified to only include claim 47 (Answer, page 3). Similarly, the final rejections under § 102(a) over Gregory and under § 103(a) over Gregory in view of Labroo have been modified to exclude claims 101 and 102, which now stand allowed (Answer, page 2, ¶(3), and page 3, ¶(6)).

OPINION

A. The Rejections under § 102(a) or § 103(a)

The examiner finds that "tropoelastin monomer is merely a precursor to elastin such that when tropoelastin is formed into a biomaterial by crosslinking or polymerization, it becomes elastin." Answer, page 4. Therefore the examiner further finds that the term "tropoelastin biomaterial," defined in appellants' specification as crosslinked or polymerized tropoelastin, is actually "elastin or elastin-based material" (*id.*). The examiner finds that Gregory is directed to the same method as claimed, using elastin or elastin-based biomaterial, and thus anticipates the claimed subject matter (*id.*).

Alternatively, the examiner recognizes that the word "tropoelastin" is not explicitly disclosed by Gregory and therefore applies Labroo for its teaching that tropoelastin has similar tissue binding properties to elastin (*id.*). Accordingly, the examiner concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of appellants' invention to have interchangeably used tropoelastin as taught by Labroo for the elastin biomaterial of Gregory (*id.*).

Appellants argue that evidence has been submitted to antedate the effective date of Gregory and thus this reference is

not available as prior art under section 102(a)(Brief, pages 13-16; Reply Brief, pages 6-8). Accordingly, the first issue that must be resolved is whether Gregory is available as prior art under 35 U.S.C. § 102(a).

Appellants state that this application is a continuation-in-part of U.S. Application No. 08/341,881, filed Nov. 15, 1994 (now U.S. Patent No. 5,989,244) and a continuation-in-part of U.S. Application No. 08/658,855 filed on May 31, 1996 (now U.S. Patent No. 5,990,379)(Brief, page 13). Appellants have noted that Application No. 08/341,881 is also the parent application of the Gregory reference (*id.*). Appellants state, and the examiner does not dispute, that the "effective date" of Gregory is May 23, 1996 (*id.*). Appellants rely on the following evidence to antedate the Gregory reference: a Declaration under 37 CFR § 1.131 by Dr. Maslen (Brief, page 13; hereafter the Maslen Declaration), a Declaration under Rule 131 by Dr. Gregory (Brief, page 14; hereafter the Gregory Declaration), a Declaration of Prior Invention in the United States to Overcome a Cited Publication (Brief, page 15; hereafter the Barofsky Declaration, dated July 12, 1999, Paper No. 13), and the exhibits attached to the Gregory

Declaration (hereafter the Exhibits; see pages 15-16 of the Brief and attachments 1-9).[3]

Upon review of appellants' evidence as a whole, we agree with the examiner that the evidence is insufficient to antedate the Gregory reference (Answer, pages 5-7). Appellants' evidence fails to establish that any embodiment of the *claimed subject matter* was conceived or reduced to practice prior to the effective date of Gregory.

The Maslen Declaration merely states that the "work in my laboratory on tropoelastin began on or about September 1995" (Maslen Declaration, ¶4). The "work...on tropoelastin" is not identified in this Declaration, nor established as within the scope of the claimed subject matter. The Maslen Declaration further states that "tropoelastin research was performed...substantially continuously during the period of September, 1996 to at least February 7, 1997" (*id.* at ¶5). This statement also fails to identify the "research" or establish that this "research" was within the scope of the claimed subject matter. Additionally, we note that this Declaration fails to

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[3]We note that appellants do not discuss or rely on the Declaration under Rule 131 dated Mar. 10, 2001, by Dr. Gregory (Paper No. 26).

account for the time period from when the work on tropoelastin began (Sep. 1995) to the tropoelastin research start (Sep. 1996)(Maslen Declaration, ¶4 and ¶5).

The previously mentioned deficiencies in the Maslen Declaration are repeated in the Gregory Declaration (see ¶4 and ¶5, referring to "work...on tropoelastin" and "tropoelastin research," respectively). Furthermore, the Gregory Declaration states that the "initial aim" of the collaborative work "was to develop a tropoelastin expression system to provide quantities of tropoelastin" to the OMLC (¶3). The Gregory Declaration fails to establish how this "initial aim" corresponds or is within the scope with the claimed subject matter. We also note that the omitted time period previously discussed (from Sep. 1995 to Sep. 1996) also has not been accounted for in ¶4 and ¶5 of the Gregory Declaration.

The Barofsky Declaration relies upon Exhibit A, a confidential Research proposal, to establish the date of conception of this invention prior to the effective date of Gregory (Barofsky Declaration, ¶3). However, this "proposal" merely states that polymerized tropoelastin "may be the optimal biomaterial" for vascular replacement and repair (Exhibit A, first paragraph). The "proposal" further states that "we propose

to initiate basic developmental work identifying processes for obtaining tropoelastin *in the first year of this proposal"* (*id.*, italics added). Finally, the "proposal" states that "[t]ropo-elastin sheets and conduits *will be evaluated* for suitability for vascular implants" (Exhibit A, last paragraph, italics added). Neither appellants nor Declarants have explained why this "proposal" establishes conception of any embodiment within the scope of the claimed subject matter (see, for example, the method for producing a biomaterial fused onto a tissue substrate as recited in claim 1 on appeal). It appears that this "proposal" merely intends to develop methods of obtaining tropoelastin, with subsequent testing/evaluation of the suitability of polymerized tropoelastin for vascular implants.

Although not discussed or relied upon by appellants (see footnote 3), the Gregory Declaration dated Mar. 14, 2001, Paper No. 26, relies upon the same Exhibit A previously discussed to establish a date of conception prior to the effective date of Gregory (¶4). Exhibits B and C attached to the Gregory Declaration of Paper No. 26 relate to activity subsequent to the effective date of the Gregory reference and add nothing to the evidence of conception (¶6).

Similarly, the attachments 1 through 9 to the Brief merely relate to appellants' attempted showing of diligence and add nothing to the evidence of conception (Brief, pages 15-16).

For the foregoing reasons and those set forth in the Answer, based on the totality of the record, we determine that appellants have not established a date of conception prior to the effective date of the Gregory reference. Accordingly, Gregory is available as prior art under 35 U.S.C. § 102(a).

Implicit in our review of the examiner's anticipation and obviousness analyses is that the claims must first have been correctly construed to define the scope and meaning of any contested limitations. *See Gechter v. Davidson*, 116 F.3d 1454, 1457, 1460 n.3, 43 USPQ2d 1030, 1032, 1035 n.3 (Fed. Cir. 1997). During examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification. *See In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995). The only contested limitation in this appeal appears to be "said biomaterial consisting essentially of tropoelastin" as recited in the claims, e.g., see claim 1 on appeal. See the Reply Brief, pages 3-5; Answer, page 4. Accordingly, we first must correctly construe the meaning of "consisting essentially of tropoelastin." The transition phrase "consisting essentially of"

has a well recognized meaning in patent jurisprudence, limiting the composition to the recited component and opening the claim to all other unlisted components that do not materially affect the basic and novel properties of the composition. *See PPG Industries Inc. v. Guardian Industries Corp.*, 156 F.3d 1351, 1354-55, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998); *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976); *and In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). As held in *Herz, supra:*

> Therefore, in construing the phrase "consisting essentially of" in appellants' claims, it is necessary and proper to determine whether their specification reasonably supports a construction that would include additives such as the dispersant copolymer of Messina.

We do not find, and appellants have not identified, any portion of their specification which would exclude any other component from the tropoelastin used in forming the biomaterial. Appellants argue that the "homopolymeric biomaterial of the rejected claims is patentably distinct from the heteropolymeric composition of Gregory" since Gregory refers to Rabaud for a method of preparing tropoelastin including fibrinogen or cryoglobulins, collagen, thrombin, and potentially a protease inhibitor (Reply Brief, pages 4-5). However, we do not find the

term "homopolymer" recited in the claims on appeal, nor do appellants provide any evidence, in the specification or otherwise, that any basic and novel properties of the biomaterial would be affected by other components such as those taught by Rabaud.

The word "biomaterial" as employed in appellants' specification is construed as a polymerized or crosslinked tropoelastin monomer (see the specification, page 8, ll. 21-page 9, l. 9; page 10, ll. 18-22; page 14, ll. 6-13; and page 21, ll. 15-20). Accordingly, we construe the claimed phrase "said biomaterial consisting essentially of tropoelastin" as meaning a polymerized and/or crosslinked material necessarily containing tropoelastin and open to the inclusion of other components.

Accordingly, in view of the claim construction discussed above, we determine that the method for producing a biomaterial fused onto a tissue substrate, as taught by Gregory for elastin or elastin-based materials, anticipates the claimed method using a tropoelastin biomaterial. As found by the examiner (Answer, page 4), tropoelastin is the uncrosslinked and unpolymerized precursor to elastin. See the specification, which teaches that "[i]n vertebrates elastin is formed through the secretion and crosslinking of tropoelastin" (page 1, ll. 15-17; see also page

16, ll. 4-6). Appellants further admit that "[i]n tissue, tropoelastin is naturally crosslinked by several tetra and bifunctional cross-links to form elastin" and appellants crosslink tropoelastin monomers with these same cross-links to form identical or nearly identical elastic matrices (specification, page 21, ll. 8-26). Therefore we agree with the examiner that a reasonable basis has been established that the products used as the biomaterial in the method of Gregory are the same or substantially the same as the biomaterial used in appellants' claimed method. *See In re Spada,* 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); *and In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus the burden of proof has been shifted to appellants, and we note that there is no evidence on this record that the products used in the method of Gregory differ substantially from the biomaterial used in the claimed method.[4]

Appellants argue that Labroo does not teach the interchangeability of tropoelastin and elastin (Brief, pages 17-

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[4]We note that appellants admit that their "artificially-crosslinked biomaterial...does possess the same polymeric structure or physical properties as elastin" (Reply Brief, page 5). Appellants also admit that elastin does comprise crosslinked tropoelastin (*id.*).

18; Reply Brief, pages 4-5). Appellants argue that Labroo offers elastin and tropoelastin as two distinct moieties, each employable as a second polypeptide monomer in the reference's claimed copolymer (*id.*). These arguments are not persuasive. Labroo specifically teaches that structural proteins including elastin and tropoelastin have "desirable physical characteristics" including the "ability to bind tissue" (col. 9, ll. 7-20). Since Gregory is directed to methods of securing or binding elastin or an elastin-based biomaterial to existing tissue (see page 4, ll. 10-19), one of ordinary skill in this art would have reasonably been motivated to use tropoelastin in place of elastin in the method of Gregory with a reasonable expectation of success in view of the teachings of Labroo.

We note that appellants have only contested the availability of Gregory as a prior art reference in the principal Brief (Answer, page 7). Appellants' arguments in the Reply Brief concerning Gregory are not persuasive in view of our claim construction as previously discussed.

For the foregoing reasons and those stated in the Answer, we determine that the examiner has established a *prima facie* case of anticipation over Gregory, as well as a *prima facie* case of obviousness over Gregory in view of Labroo. We note that

appellants have submitted s Declaration under 37 CFR § 1.132 by Dr. Gregory (Paper No. 13, dated July 12, 1999). However, appellants have not relied on this evidence in either the Brief or Reply Brief. Furthermore, this Declaration is only directed to one possible method of preparation of elastin as taught by the Gregory reference (see Gregory, pages 7-8). Additionally, this Declaration merely compares the elastin of Rabaud with the "invention as described by the present application," not the invention *as now claimed.*

Based on the totality of the record, we affirm the examiner's rejection of claims 1-13, 15-24, 36-39, 41-55, 74, 76-100, 103 and 104 under 35 U.S.C. § 102(a) as anticipated by Gregory, or alternatively under 35 U.S.C. § 103(a) over Gregory in view of Labroo.

B. The Rejection under § 102(b)

The examiner rejects claim 47 under section 102(b) over the admitted prior art on page 1, ll. 12-23, of the specification, where appellants disclose that the natural process of elastin formation in vertebrates occurs through the secretion and crosslinking of tropoelastin (Answer, page 5).

Appellants argue that the biomaterial of claim 47 consists essentially of tropoelastin (a homopolymer) and is not naturally

occurring elastin (a hetero- or co-polymer)(Reply Brief, page 10). This argument is not persuasive in view of our previously discussed claim construction. The first claimed step of "providing a polymerizable monomer consisting essentially of tropoelastin" is described or taught by the natural secretion of tropoelastin (specification, page 1, l. 16). The second claimed step is accomplished naturally by crosslinking (specification, page 1, l. 16; page 9, ll. 1-4; see the claim construction of "consisting essentially of" above). The third claimed step ("forming a biomaterial") merely reads on the polymer formation which can be considered as a layer (see the specification, page 9, ll. 5-9). Accordingly, we agree with the examiner that all of the limitations of properly construed claim 47 have been described or taught by the admitted naturally occurring process taught on page 1 of the specification.

For the foregoing reasons and those stated in the Answer, we affirm the examiner's rejection of claim 47 under section 102(b) over the admitted prior art.

C. Summary

The rejections of claims 1-13, 15-24, 36-39, 41-55, 74, 76-100, 103 and 104 under 35 U.S.C. § 102(a) over Gregory or, in the alternative, under 35 U.S.C. § 103(a) over Gregory in view of

Labroo, are affirmed. The rejection of claim 47 under 35 U.S.C. § 102(b) over the admitted prior art is affirmed.

The decision of the examiner is affirmed.

Appeal No. 2005-0419
Application No. 08/797,770

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv)(effective Sep. 13, 2004; 69 Fed. Reg. 49960 (Aug. 12, 2004); 1286 Off. Gaz. Pat. Office 21 (Sep. 7, 2004)).

AFFIRMED

EWARD C. KIMLIN)
Administrative Patent Judge)
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THOMAS A. WALTZ) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND
) INTERFERENCES
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ROMULO H. DELMENDO)
Administrative Patent Judge)

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